

# Notice of Allowability

Application No.

09/558,149

Examiner

Valarie Bertoglio

Applicant(s)

NICOLAIDES ET AL.

Art Unit

1632

## -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the amenddment filed 05/01/2007.
2. ☒ The allowed claim(s) is/are 60,61,71-75,86-87,89-90,92-93.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All b) ☐ Some\* c) ☐ None of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

### Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO/SB/08),  
Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413),  
Paper No./Mail Date \_\_\_\_\_
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

### EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Sarah Kagan on 06/11/2007.

The application has been amended as follows:

Claims 60,61,71,75 and 89 have been amended to read as follows:

60. A transgenic mouse wherein the germ and somatic cells of said mouse comprise a transgene comprising a polynucleotide encoding a dominant negative form of a human PMS2 mismatch repair protein, wherein the protein consists of the first 133 amino acids of human PMS2, and wherein said polynucleotide is operably linked to a promoter, wherein the cells of said mouse that express said transgene are hypermutable.

61. A transgenic mouse produced by a process comprising the steps of: introducing a transgene comprising a polynucleotide encoding a dominant negative form of a human PMS2 mismatch repair protein into a fertilized mouse egg, wherein the protein consists of the first 133 amino acids of human PMS2, and wherein said polynucleotide is operably linked to a promoter, implanting the fertilized egg into a pseudopregnant female; and allowing said mouse egg to develop into a transgenic mouse comprising cells that express the transgene, wherein the cells of said mouse that express the transgene are hypermutable.

71. (Currently Amended) A method for generating a mutation in a gene of interest comprising the steps of:

introducing a transgene comprising a polynucleotide encoding a dominant negative form of a human PMS2 mismatch repair protein into a fertilized mouse egg, wherein the protein consists of the first 133 amino acids of human PMS2, and wherein said polynucleotide is operably linked to a promoter;

implanting the fertilized egg into a pseudopregnant female;

allowing said fertilized mouse egg to develop into a transgenic mouse comprising cells that express the transgene, wherein said cells that express the transgene are hypermutable; and testing the mouse to determine whether the gene of interest has a mutation.

75. The method of claim 71 wherein the step of testing comprises analyzing a phenotype conferred by the gene of interest.

89. The mouse of claim 60 wherein said polynucleotide comprises a truncation mutation at codon 134 of SEQ ID NO: 1.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Valarie Bertoglio whose telephone number is (571) 272-0725. The examiner can normally be reached on Mon-Thurs 5:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Valarie Bertoglio, Ph.D./  
Primary Examiner  
Art Unit 1632